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10/563,687	12/11/2006	Jacques Benveniste	NY-GRYN 229-US	3404

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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,687	BENVENISTE, JACQUES	
	Examiner	Art Unit	
	LISA V. COOK	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Amendment Entry

1. Applicant's response to the Office Action mailed 5/1/08 is acknowledged (papers filed 9/24/08 and 1/30/09). In the amendment filed therein claims 1, 5, and 7 were modified. Claim 2 was canceled. Currently claims 1 and 3-9 are pending and under consideration.

2. Rejections and/or objections of record not reiterated herein have been withdrawn.

NEW GROUNDS OF REJECTIONS NECESSITATED BY AMENDMENT

Claim Objections

3. Claim 3 is objected to because of the following informalities: Claim 3 is dependent on **cancelled** claim 2. It appears that Applicant intends to have this claims depend on claim 1. Appropriate correction is required. For the purpose of examination claim 3, has been treated as dependent on claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1 and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Claims 3-9 are rejected as being dependent on claim 1).

A. Claim 1 is vague and indefinite because the method steps in the body of the claim do not positively correlate or recite a resolution step that relates to the preamble. As recited claim 1 merely reads on the detection of PMN adhesion to plastic in the presence of an extract.

However, the preamble is drawn to "diagnosing intolerance". This makes the claim ambiguous and the metes and bounds of the claim can not be determined. It is suggested that a correlation/resolution step directed to the preamble be added to the final method steps in order to obviate this rejection. For example, Applicant could add "wherein increased adhesion of PMNs is indicative of a subject's increased intolerance". This is supported by the disclosure on page 4 lines 7-8. Please correct. Applicant is *cautioned* not to introduce new matter when modifying the claims.

Please Note: The body of the method does not require the measurement of a subject's intolerance. Claim 1 merely requires PMNs adhesion or the assaying of PMNs adhesion in the presence of at least an extract of a specified substance. Therefore the prior art has been applied with respect to PMNs adhesion measurements.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1, 3, 4, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitani et al. (Rheumatol. Int., 2001, Vol.2001, pages 180-185).

Mitani et al. teach methods of measuring PMN adhesion in ninety six-well microtiter plates (claim 4). See abstract and page 181, 2nd column, 1st paragraph.

Heparinized venous blood (Applicant's leucocyte sample preparation – whole blood encompasses leucocytes) from normal human donors was utilized to produce polymorphonuclear neutophils (PMNs). See page 181, 1st column, preparation of PMN.

The PMNs were incubated with proteglycans, SE (an extract of cartilage surface small proteoglycans), or DPBS. (Reading on Applicant's specified substance) Activated cells or adherent cells were quantified by the bicinchoninic acid (BCA) protein assay (claim 9). Adhesion was measure by optical absorbance at 562nm and 490nm (claim 8). See abstract and page 181, 2nd column, 1st paragraph abstract.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

II. Claim 5 is rejected under 35 U.S.C. 103(b) as being unpatentable over Mitani et al. (Rheumatol. Int., 2001, Vol.2001, pages 180-185) in view of Higashi-Okai et al. (Journal of Fermentation and Bioengineering, Vol.85, No.6, pages 555-558, 1998).

Please see Mitani et al. as set forth above.

Mitani et al. differ from the instant invention in not specifically teaching the measurement of a food extract.

However, Higashi-Okai et al. teaches that tea is the most ancient and popular beverage in the world. Further, tea extracts (food extract) can be utilized to study in vitro functional activation of human PMNs and anti-inflammatory activities. See page 555, 1st column.

Higashi-Okai et al. demonstrate that pheophytin a and b from the non-polyphenolic fraction of green tea have potent suppressive activities against the activation of human PMNs functions such as oxygen radical generation, IL-1β release, and chemotaxis which are associated with inflammatory reactions. See page 557, 1st column – Discussion. The suppressive effects of pheophytin a and b results indicated that the combined intake of catechins in the water-soluble fraction and pheophytins in the non-poly- phenolic fraction of green tea might show much stronger anti-inflammatory activity. See page 557-558. The suppressive effects of pheophytin a and b on chemiluminescence generation in human PMNs seem to contribute to the anti-inflammatory activity against oxygen radical-induced tissue injury or inflammation. See page 557, 2nd column, 1st paragraph.

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to utilize food extracts like green tea extracts as taught by Higashi-Okai et al. in the PMNs activation/adhesion procedure of Mitani et al. because Higashi-Okai et al. taught that tea extracts (food extract) can be utilized to study in vitro functional activation of human PMNs and anti-inflammatory activities. See page 555, 1st column.

One of ordinary skill in the art would have been motivated to do this in order to measure anti-inflammatory activities and develop more effective suppressive effects for the evaluation and treatment of tissue injury and/or inflammation. For example, see page 557, 2nd column, 1st paragraph.

III. Claims 6 and 7 are rejected under 35 U.S.C.103 (a) as being unpatentable over Mitani et al. (Rheumatol. Int., 2001, Vol.2001, pages 180-185) in view of Higashi-Okai et al. (Journal of Fermentation and Bioengineering, Vol.85, No.6, pages 555-558, 1998) and further in view of Hoy et al. (Clin Chem Lab Med 2002, Vol. 40, No.1, pages 2-8).

Please see Mitani et al. (Rheumatol. Int., 2001, Vol.2001, pages 180-185) in view of Higashi-Okai et al. (Journal of Fermentation and Bioengineering, Vol.85, No.6, pages 555-558, 1998) as set forth above.

Mitani et al. (Rheumatol. Int., 2001, Vol.2001, pages 180-185) in view of Higashi-Okai et al. (Journal of Fermentation and Bioengineering, Vol.85, No.6, pages 555-558, 1998) differ from the instant invention in not specifically teaching PMNS activation/adhesion measurements by assaying intracellular markers, like myeloperoxidase for PMNs.

However, Hoy et al. teach that myeloperoxidase (MPO) is a glycoprotein released by activated polymorphonuclear neutrophils (PMNs). The involvement of MPO has been described in numerous diseases such as atherosclerosis, lung cancer, Alzheimer's disease and multiple sclerosis. MPO is taught to be a new clinical marker for future therapeutic targets. See abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to detect MPO released by activated PMNs as exemplified by Hoy et al. in the PMNs activation/adhesion procedure of Mitani et al. because Hoy et al. taught that MPO is involved in numerous diseases such as atherosclerosis, lung cancer, Alzheimer's disease and multiple sclerosis. Further, MPO may be useful as a new clinical marker for future therapeutic targets. See abstract.

Hoy s et al. employed the marker MPO. However, the substitution of other known marker of PMNs as recited in claim 7, to produce predictable results similar to MPO is deemed obvious absent evidence to the contrary. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Thus, the use of the known markers for PMNs is viewed as a simple substitution of one known, equivalent marker for another to obtain predictable results.

Response to Arguments

Applicant's arguments and amendments have been carefully considered and found persuasive. Accordingly new rejections are presented herein.

7. For reasons aforementioned, no claims are allowed.

Remarks

8. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Tellado et al. (Journal of Leukocyte Biology, Vol.50, 1991, pages 547-553) disclose PMN activation in anergic patients.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Patent Examiner
Art Unit 1641
Remsen 3C-59
571-272-0816

/Lisa V. Cook/
Primary Examiner, Art Unit 1641